

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PEGGY B. BUMGARNER and)	
ROGER D. BUMGARNER,)	Case No.: 1:13-cv-12679 (RWZ)
)	
Plaintiffs,)	
)	
v.)	MDL No. 2419
)	Dkt. No. 1:13-md-2419 (RWZ)
AMERIDOSE, LLC, MEDICAL SALES)	
MANAGEMENT, INC., MEDICAL SALES)	
MANAGEMENT SW, INC., GDC)	
PROPERTIES MANAGEMENT, LLC,)	
ARL BIO PHARMA, INC. D/B/A)	
ANALYTICAL RESEARCH LABORATORIES,)	
BARRY J. CADDEN, GREGORY)	
CONIGLIARO, LISA CONIGLIARO CADDEN,)	
DOUGLAS CONIGLIARO, CARLA)	
CONIGLIARO, GLENN A. CHIN, and)	
SPECIALTY SURGERY CENTER, PLLC,)	
KENNETH LISTER, MD, PC, and)	
KENNETH R. LISTER, MD,)	
)	
Defendants.)	

**ANSWER OF SPECIALTY SURGERY CENTER, CROSSVILLE, PLLC,
KENNETH R. LISTER, MD, AND KENNETH LISTER, MD, PC**

For their Answer to the Plaintiffs' Complaint, the Defendants Specialty Surgery Center, Crossville, PLLC ("SSC"), Kenneth R. Lister, MD ("Dr. Lister"), and Kenneth Lister, MD, PC ("Dr. Lister's Practice") (collectively, the "Defendants"), state as follows:

INTRODUCTION

1. The Defendants admit that the Centers for Disease Control and Prevention (“CDC”) reported that individuals in more than 20 states were affected by the 2012 fungal meningitis outbreak and that the outbreak caused 64 deaths. The Defendants admit that the CDC has reported that 751 people have been diagnosed with fungal meningitis, fungal infections, and/or abscesses as part of the outbreak.

2. The Defendants admit that the CDC and the Food and Drug Administration (“FDA”) reported finding fungus in three lots of methylprednisolone acetate (“MPA”) from the New England Compounding Pharmacy, Inc. d/b/a the New England Compounding Center (“NECC”). The Defendants admit that that the CDC and FDA concluded that the MPA from NECC caused the fungal meningitis outbreak and resulting injuries and deaths. The Defendants are without knowledge or information sufficient to form a belief as to whether NECC’s facility was unsterile at the time the three recalled lots were compounded and was the source of the fungus that contaminated the vials holding the MPA.

3. The Defendants admit, based upon information and belief, that NECC recalled the steroid after some patients were exposed to contaminated doses.

PARTIES

4. The Defendants admit, based upon information and belief, the allegations of paragraph 4.

5. The Defendants admit, based upon information and belief, the allegations of paragraph 5.

6. The Defendants admit, based upon information and belief, the allegations of paragraph 6.

7. The Defendants admit, based upon information and belief, the allegations of paragraph 7.

8. The Defendants admit, based upon information and belief, the allegations of paragraph 8.

9. The Defendants admit, based upon information and belief, the allegations of paragraph 9.

10. The Defendants admit, based upon information and belief, that Barry Cadden is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. The Defendants admit, based upon information and belief, that Barry Cadden is a citizen and resident of the Commonwealth of Massachusetts. The Defendants admit, based upon information and belief, that Barry Cadden is the President of NECC. The Defendants admit, based upon information and belief, that, until October 2012, Barry Cadden was NECC's Licensed Pharmacist Manager of Record. The Defendants admit, based upon information and belief, that Barry Cadden is a Manager of Ameridose, LLC ("Ameridose"). The Defendants admit, based upon information and belief, that Barry Cadden is the Treasurer and a Director of both Medical Sales Management, Inc. ("MSM") and Medical Sales Management SW, Inc. ("MSMSW"). The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10.

11. The Defendants admit, based upon information and belief, that Gregory Conigliaro is a citizen and resident of the Commonwealth of Massachusetts. The

Defendants admit, based upon information and belief, that Gregory Conigliaro is Vice President, Secretary, Treasurer, registered agent, and a Director of NECC. The Defendants admit, based upon information and belief, that Gregory Conigliaro is a Manager of Ameridose. The Defendants admit, based upon information and belief, that Gregory Conigliaro is the Secretary and a Director of both MSM and MSMSW. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11.

12. The Defendants admit, based upon information and belief, that Lisa Conigliaro Cadden is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. The Defendants admit, based upon information and belief, that Lisa Conigliaro Cadden is a citizen and resident of the Commonwealth of Massachusetts. The Defendants admit, based upon information and belief, that Lisa Conigliaro Cadden is a Director of NECC. The Defendants admit, based upon information and belief, that, until October 2012, Lisa Conigliaro Cadden was a pharmacist at NECC. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12.

13. The Defendants admit, based upon information and belief, the allegations of paragraph 13.

14. The Defendants admit, based upon information and belief, the allegations of paragraph 14.

15. The Defendants admit, based upon information and belief, the allegations of paragraph 15.

16. No response is required to paragraph 16.

17. Admitted.

18. The Defendants deny that Dr. Lister's Practice's principal place of business is in Crossville, Tennessee. The Defendants admit that Dr. Lister's Practice's registered agent is Dr. Lister at 8317 Neubert Springs, Rd., Knoxville, Tennessee 37920.

19. The Defendants admit that Dr. Lister is an individual residing at 8317 Neubert Springs, Rd., Knoxville, Tennessee 37920 and is a citizen and resident of Tennessee. The Defendants deny that Dr. Lister was an employee of SSC or Dr. Lister's Practice. The Defendants admit that Dr. Lister is a medical doctor and practices in the specialty of anesthesiology. The Defendants admit that Dr. Lister was involved in the day-to-day operations of SSC.

20. No response is required to paragraph 20.

JURISDICTION AND VENUE

21. Admitted, based upon the rulings of the Court to this point in the MDL.

22. Admitted, based upon the rulings of the Court to this point in the MDL.

23. Admitted.

24. The Defendants are without knowledge or information sufficient to form a belief as to the existence of contractual indemnification obligations between NECC and Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC Properties Management, LLC ("GDC"), and MSM. The Defendants admit, based upon information and belief, that some, if not all, of the aforementioned individuals are insureds under NECC's insurance policies.

25. Denied.

26. The Defendants deny that the Honorable F. Dennis Saylor is currently presiding over the MDL. The Defendants admit the remaining allegations of paragraph 26.

27. Denied.

28. The Defendants admit that they have filed proofs of claims in NECC's bankruptcy case.

29. The Defendants are without knowledge or information sufficient to form a belief as to the meaning of the phrase "based on the contaminated MPA purchased from NECC." Accordingly, the Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 29.

30. Denied. The Plaintiffs have already filed proofs of claims in NECC's bankruptcy case.

31. Admitted. The order speaks for itself.

32. Denied.

33. Admitted.

34. The Defendants admit that Dr. Lister administered MPA to patients in Tennessee. The Defendants admit that SSC selected and purchased MPA from NECC for use in Tennessee. The Defendants deny the remaining allegations of paragraph 34 and specifically deny selling MPA to any patients. The remaining allegations of paragraph 34 are not asserted against the Defendants. No response is required.

35. The Defendants admit that they are subject to the jurisdiction of the District Court for the Middle District of Tennessee. The Defendants deny any and all allegations of wrongdoing and specifically deny that any of their allegedly wrongful acts

or omissions were a legal cause of the Plaintiffs' alleged injuries or damages. The remaining allegations of paragraph 35 are not asserted against the Defendants. No response is required.

36. The allegations of paragraph 36 are not asserted against the Defendants. No response is required.

STATEMENT OF FACTS

A. Relevant Background

37. Admitted.

38. The Defendants admit, based upon information and belief, the allegations of paragraph 38.

39. The Defendants admit, based upon information and belief, that, until at least October 2012, Barry Cadden was a licensed pharmacist, NECC's President, and NECC's Pharmacy Manager of Record. The Defendants are without knowledge or information sufficient to form a belief as to whether Barry Cadden compounded medications, including MPA, at NECC.

40. Admitted. The regulation speaks for itself.

41. The Defendants admit that the regulation states, in part, that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." The regulation speaks for itself.

42. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 42.

43. The Defendants admit, based upon information and belief, that Glenn Chin and Lisa Cadden were licensed pharmacists. The Defendants admit, based upon

information and belief, that Glenn Chin compounded medications, including MPA, at NECC. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 43.

44. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 44.

45. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 45.

46. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 46.

47. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 47.

48. The Defendants admit, based upon information and belief, the allegations of paragraph 48.

49. The Defendants admit, based upon information and belief, that MSM and/or MSMSW sold and/or marketed NECC products through September 2012. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 49.

50. The Defendants admit, based upon information and belief, the allegations of paragraph 50.

51. Admitted.

52. Admitted.

53. The Defendants admit that the website of ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") states that ARL follows USP

monographs/general chapters and that ARL has a formal Quality Assurance Program. The Defendants are without knowledge or information sufficient to form a belief as to whether ARL's website states that the Quality Assurance Program complies with USP monographs/general chapters.

54. The Defendants admit, based upon information and belief, the allegations of paragraph 54.

55. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 55.

56. The Defendants admit, based upon information and belief, that NECC leased the Framingham, Massachusetts facility on Waverly Street from GDC. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 56.

57. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 57.

58. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 58.

59. The Defendants admit, based upon information and belief, that NECC and Glenn Chin compounded MPA. The Defendants admit, based upon information and belief, that ARL tested MPA. The Defendants admit, based upon information and belief, that NECC distributed MPA. The Defendants admit, based upon information and belief, that MSM and/or MSMSW marketed and sold MPA. The Defendants admit that MPA is a steroid used to treat back and neck pain and is administered via injection. The

Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 59.

60. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 60.

61. The Defendants admit, based upon information and belief, that NECC compounded MPA at its Framingham, Massachusetts facility and sold it to health care providers in more than 20 states until September 2012. The Defendants are without knowledge or information sufficient to form a belief as to whether NECC compounded or sold any MPA in October 2012.

62. The Defendants admit, based upon information and belief, that the Tennessee Department of Health ("Tenn. DoH") notified the CDC of a patient with fungal meningitis following an epidural steroid injection. The Defendants admit, based upon information and belief, that the CDC's investigation of the outbreak began in September 2012. The Defendants are without knowledge or information sufficient to form a belief as to the exact timing of the Tenn. DoH's notification of the CDC or confirmation that the index patient's meningitis was caused by fungus.

63. The Defendants admit, based upon information and belief, the allegations of paragraph 63.

64. Admitted.

65. Admitted.

66. The Defendants admit, based upon information and belief, that NECC voluntarily surrendered its license on October 3, 2012.

67. Admitted.

68. The Defendants admit, based upon information and belief, the allegations of paragraph 68.

69. The Defendants admit, based upon information and belief, that NECC sent ARL two five mL vials of MPA from Lot #052212012@51, BUD 11/17/12 for sterility testing. The Defendants are without knowledge or information sufficient to form a belief as to the total number of vials in Lot #052212012@51, BUD 11/17/12.

70. The Defendants admit, based upon information and belief, the allegations of paragraph 70.

71. The Defendants admit, based upon information and belief, the allegations of paragraph 71.

72. The Defendants admit that USP 71 recommends testing of 2% or at least 20 vials for lots of greater than 6,000 vials.

73. The Defendants admit, based upon information and belief, that NECC sent ARL two five mL vials of MPA from Lot #08102012@51, BUD 2/6/2013 for sterility testing. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 73.

74. The Defendants admit that at least some of the Microbiology Reports issued to NECC by ARL indicate that a USP 71 compliant sterility testing method was used. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 74.

75. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 75.

76. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 76.

77. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 77.

78. Admitted.

79. The Defendants admit that the article contains the language quoted in paragraph 79. The Defendants are without knowledge or information sufficient to form a belief as to Mr. Kupiec's knowledge at the time he wrote the article.

80. Admitted.

81. The Defendants admit, based upon information and belief, that ARL allowed NECC to submit inadequate numbers of samples for sterility testing, which did not comply with USP 71 recommendations. The Defendants are without knowledge or information sufficient to form a belief as to whether ARL allowed any other compounding pharmacies to submit an inadequate number of samples.

82. The Defendants admit that MSM and/or MSMSW distributed marketing materials to customers and potential customers touting the cleanliness of the NECC facility. The Defendants admit that the FDA reported that NECC's internal environmental monitoring program yielded microbiological isolates on multiple occasions between January and August 2012. The Defendants admit that the FDA reported that NECC did not investigate or identify the microbiological isolates, or take corrective actions to prevent contamination of the sterile drug products. The Defendants admit, based upon information and belief, that NECC continued to compound MPA despite these findings.

The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 82.

B. Defendants Ignored Safety Standards by Producing Drugs in a Non-Compliant Facility

83. The Defendants admit, based upon information and belief, that the FDA and Massachusetts Board of Registration in Pharmacy (“Mass. BoP”) reported identifying “serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public’s health and safety at risk” at NECC. The Defendants admit that both agencies have release reports from their investigation. The Defendants are without knowledge or information sufficient to form a belief whether either agency concluded that “bacteria and mold festered throughout NECC [sic] facility and equipment.”

84. Admitted.

85. Admitted.

86. Admitted, based upon reports from these agencies.

87. Admitted.

88. The Defendants admit, based upon information and belief, the allegations of paragraph 88.

89. The Defendants admit, based upon information and belief, the allegations of paragraph 89.

90. The Defendants admit, based upon information and belief, the allegations of paragraph 90.

91. The Defendants are without knowledge or information sufficient to form a belief as to whether NECC operated under the same roof as the used mattress

processing facility. The Defendants admit, based upon information and belief, the remaining allegations of paragraph 91 regarding the FDA's findings.

92. The Defendants admit, based upon information and belief, the allegations of paragraph 92.

93. The Defendants admit that MSM and/or MSMSW marketed products compounded by NECC. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 93.

C. Defendants Disregarded Prior Complaints and Inspections by Continuing Impermissible Conduct and Ignoring Safety Risks

94. The Defendants deny having any knowledge of the events described in paragraph 94 prior to the recall, such that it was impossible for them to "ignore" those events. The Defendants admit, based upon information and belief, that the FDA received reports of adverse events regarding NECC in 2002. The Defendants admit, based upon information and belief, that, in 2002, a patient contracted meningitis and died after receiving MPA compounded by NECC. The Defendants are without knowledge or information sufficient to form a belief as to whether the NECC MPA caused the patient's meningitis or death. The Defendants admit, based upon information and belief, that in October 2002, the FDA informed the Mass. BoP of a report of an incident involving NECC MPA, which is the same steroid that caused the fungal meningitis outbreak.

95. The Defendants admit that a 2004 report from the Mass. BoP reported that an unidentified medical facility conducted endotoxin testing on a betamethasone repository from NECC, which came back positive for endotoxins. The Defendants admit that, according to the 2004 report, NECC and Barry Cadden could not produce various

records for the betamethasone repository, including sterility testing results. The Defendants are without knowledge or information sufficient to form a belief as to whether NECC met “accepted standards that year for making the steroid.”

96. The Defendants admit, based upon information and belief, that Pharmacy Support Inc. (“PSI”), an outside evaluation firm, sent a letter to NECC in 2006 reporting that PSI observed that NECC continued to have significant gaps in its sterile compounding process. The Defendants admit that the FDA issued a warning letter to NECC in 2006. The Defendants are without knowledge or information sufficient to form a belief as to whether the FDA issued more than one warning letter.

97. The Defendants admit, based upon information and belief, that NECC solicited out-of-state prescriptions for office use and used forms that had not been approved by the Mass. BoP. The Defendants admit, based upon information and belief, that NECC and Barry Cadden were aware of complaints regarding this practice and NECC’s promotional materials and methods, but apparently disregarded them. The Defendants deny that they were aware of these complaints or the alleged impropriety of NECC’s promotional materials and methods, or that they disregarded them.

D. Peggy Bumgarner’s Exposure to this Toxin

98. The Defendants admit that SSC received contaminated MPA from NECC in 2012. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 98.

99. Admitted.

100. The Defendants are without knowledge or information sufficient to form a belief as to Ms. Bumgarner’s knowledge. The Defendants admit, based upon

information and belief, that the MPA Ms. Bumgarner received came from one of the contaminated lots of MPA that was recalled by NECC.

101. The Defendants admit, based upon information and belief, that Ms. Bumgarner was admitted to Cumberland Medical Center on October 6, 2012. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 101.

102. The Defendants admit, based upon information and belief, that Ms. Bumgarner was discharged from Cumberland Medical Center on October 12, 2012.

103. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 103.

104. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 104.

105. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 105.

106. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 106.

107. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 107.

108. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 108.

109. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries or damages.

COUNT I
NEGLIGENCE
(Against All NECC Related Defendants)

110. to 116. The allegations of paragraphs 110 to 116 are not asserted against the Defendants. No response is required.

COUNT II
NEGLIGENCE PER SE
(Against All NECC Related Defendants)

117. to 121. The allegations of paragraphs 117 to 121 are not asserted against the Defendants. No response is required.

COUNT III
NEGLIGENT SUPERVISION
(Against All NECC Related Defendants)

122. to 126. The allegations of paragraphs 122 to 126 are not asserted against the Defendants. No response is required.

COUNT IV
Public Nuisance
(Against All NECC Related Defendants)

127. to 135. The allegations of paragraphs 127 to 135 are not asserted against the Defendants. No response is required.

COUNT IV
Product Liability Claims
(Against SSC, Dr. Lister, and Dr. Lister's Practice)

Pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all product liability claims against Defendants other than SSC, including Dr. Lister and Dr. Lister's Practice, have been dismissed.

136. Admitted.

137. Admitted.

138. The Defendants admit that the section imposes an automatic stay with various exceptions. The statutory section speaks for itself.

139. The Defendants admit that the section imposes an automatic stay with various exceptions. The statutory section speaks for itself.

140. The Defendants admit, based upon information and belief, that NECC is not presently compounding medications.

141. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 141.

142. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 142.

143. Denied.

144. Denied.

145. Admitted. The Court's order speaks for itself.

146. The Defendants admit that SSC purchased the MPA administered to Ms. Bumgarner from NECC. The Defendants deny that Dr. Lister procured the MPA.

147. The Defendants admit, based upon information and belief, that the MPA administered to Ms. Bumgarner was contaminated by NECC. The Defendant's admit, based upon information and belief, that the MPA was in substantially the same condition when it was administered to Ms. Bumgarner as when it left NECC. MPA purchased from NECC arrived in sealed packages containing sealed individual vials labeled as injectable. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants deny the suggestion that they

engaged in any wrongdoing in procuring the MPA or in administering the MPA during Ms. Bumgarner's procedures.

148. The Defendants admit that SSC and Dr. Lister charged Ms. Bumgarner and/or her insurer for the professional services associated with her epidural steroid injection procedure. The Defendants deny that they charged Ms. Bumgarner or her insurers for the MPA itself.

149. Denied.

150. Denied.

151. Denied.

152. The Defendants deny that NECC cannot be served with process. NECC can be served with process under the Tennessee Long-Arm Statute, codified at Tenn. Code Ann. § 20-2-225. Upon the filing of a motion for relief from the automatic stay, the Plaintiffs' claims can be pursued against NECC. The Defendants deny that the Plaintiffs can pursue products liability claims against the Defendant healthcare providers.

153. The Defendants admit, based upon information and belief, that the MPA administered to Ms. Bumgarner was contaminated. The Defendants deny any suggestion that they engaged in any wrongdoing in procuring the MPA or in using the MPA during Ms. Bumgarner's procedure.

154. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 154.

155. The Defendants deny that they sold MPA or that they breached any warranty, express or implied, to Ms. Bumgarner.

156. Denied. The Defendants further deny the suggestion that they engaged in any wrongdoing in procuring the MPA or in using the MPA during Ms. Bumgarner's procedure.

COUNT V
OTHER CLAIMS AGAINST SSC AND DR. LISTER

157. Denied.

158. Denied.

159. Denied.

160. The Defendants deny any and all allegations of wrongdoing and specifically deny the allegations of wrongdoing in paragraph 160, subparagraphs a. through d. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries or damages.

161. The Defendants deny any and all allegations of wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of Ms. Bumgarner's alleged injuries or damages.

162. The Defendants admit that SSC's Nursing Director was an employee of SSC. The Defendants deny that Dr. Lister was an employee of SSC. He was a member of SSC. The Defendants admit that if the Plaintiff establishes an employment or agency relationship, the Defendants may be liable for the actions of their employee or agent.

COUNT VIII
COMPLIANCE WITH STATUTORY NOTICE REQUIREMENT

163. The Defendants deny that the Plaintiffs have complied with Tenn. Code Ann. § 29-26-121, as set forth more fully in their Motion to Dismiss at Dkt. 770. The Defendants acknowledge that the Court denied the Motion to Dismiss in part, but

hereby reserve, do not waive, and reassert any and all defenses previously asserted based on the Plaintiffs' failure to comply with Tenn. Code Ann. § 29-26-121, and adopt and incorporate all previous motions to dismiss or identification of § 29-26-121 and § 29-26-122 defenses as if stated fully herein.

164. The Defendants admit that they received presuit notice letters dated May 28, 2013, and that Exhibit A to the Plaintiffs' Complaint appears to include true and accurate copies of those letters. The Defendants deny that the letters comply with Tenn. Code Ann. § 29-26-121.

165. The Defendants admit that they received presuit notice letters dated May 28, 2013, and that Exhibit B to the Plaintiffs' Complaint appears to contain true and accurate copies of those letters. The Defendants deny that the letters comply with Tenn. Code Ann. § 29-26-121.

166. The Defendants admit that they received presuit notice letters dated May 28, 2013, and that Exhibit C to the Plaintiffs' Complaint appears to contain true and accurate copies of those letters. The Defendants deny that the letters comply with Tenn. Code Ann. § 29-26-121.

167. Denied.

168. Admitted.

DAMAGES

169. Denied.

170. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 170 regarding Mr. Bumgarner's

alleged injuries but affirmatively state that they did not act wrongfully or legally cause any injury to the Plaintiffs.

PRAYER FOR RELIEF

171. The Defendants deny that the Plaintiffs are entitled to any recovery from them under any legal theory.

172. The Defendants deny that the Plaintiffs are entitled to punitive damages against these Defendants. None of the Defendants' alleged wrongdoing rose to the level of being intentional, fraudulent, malicious, or reckless.

173. No response is required to paragraph 173.

174. The Defendants deny that the Plaintiffs are entitled to any legal recovery from them under any legal theory.

175. The Defendants deny that the Plaintiffs are entitled to any recovery from them under any legal theory.

ADDITIONAL PARAGRAPHS

The Defendants hereby adopt and incorporate the section of their Answer to the Master Complaint titled "Additional Paragraphs" as if stated fully herein.

AFFIRMATIVE DEFENSES

The Defendants hereby adopt and incorporate the section of their Answer to the Master Complaint titled "Affirmative Defenses" as if stated fully herein.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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***Attorneys for the Tennessee Clinic
Defendants***

* Admitted pursuant to MDL Order No. 1.

** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 30th day of September, 2014.

/s/ Chris J. Tardio

Chris J. Tardio